IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Norfolk Division

G.D. SEARLE LLC and PFIZER ASIA PACIFIC PTE. LTD. Plaintiffs, v. LUPIN PHARMACEUTICALS, INC., TEVA PHARMACEUTICALS USA, INC., MYLAN PHARMACEUTICALS INC., WATSON LABORATORIES, INC., APOTEX INC., and APOTEX CORP., Defendants.	**PUBLIC VERSION** Civil Action No. 2:13-cv-121

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT OF INFRINGEMENT

Plaintiffs G.D. Searle Inc. and Pfizer Asia Pacific Pte. Ltd. (collectively "Pfizer") submit this memorandum in support of their motion, pursuant to Fed. R. Civ. P. 56 and paragraph 9 of this Court's June 17, 2013 Rule 16(b) Scheduling Order (Doc. 80), for summary judgment that by selling the generic celecoxib products which are the subject of this litigation [redacted], defendants Lupin Pharmaceuticals, Inc. ("Lupin"), Teva Pharmaceuticals USA, Inc. ("Teva"), Mylan Pharmaceuticals Inc. ("Mylan"), Apotex Inc. and Apotex Corp. (together "Apotex"), and Watson Laboratories, Inc. ("Watson") will induce patients to directly infringe the claims of Pfizer's U.S. Patent No. RE44,048 ("the '048 patent").

This matter is set for a bench trial on February 25, 2014. Because all parties have a strong interest in having this matter timely resolved to provide certainty to the market, Pfizer moves for summary judgment in an effort to streamline the trial.

INTRODUCTION

Defendants have submitted Abbreviated New Drug Applications ("ANDAs") to the U.S. Food and Drug Administration ("FDA") seeking approval to market generic versions of Pfizer's Celebrex® product. Defendants' proposed generic products contain celecoxib, the active ingredient in Celebrex®, the use of which is claimed in Pfizer's '048 patent. [redacted]

The use of celecoxib for these indications is covered by the claims of the '048 patent.[2]

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1 [redacted]

2 "The FDA-approved label for an approved drug indicates whether the FDA has approved a particular method of use for that drug." *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1322 (Fed. Cir. 2012).

The supporting expert declarations of Drs. Marc C. Hochberg (rheumatologist), Robin J. Hamill-Ruth (pain medicine) and James A. Simon (gynecologist) filed in support of this memorandum demonstrate that administration of defendants' generic celecoxib products to patients to treat OA, RA, JRA, AS, AP and PD [redacted] will directly infringe claim 21 ("a method of treating OA"), claim 22 ("a method of treating RA"), claim 23 ("a method of treating juvenile arthritis" ("JA")), claim 24 ("a method of treating spondyloarthropathy" ("SpA")), claim 20 ("a method of treating pain"), and claim 25 ("a method of treating menstrual cramps") of the '048 patent, *under any of the constructions of the claims proposed by the parties*. By selling their generic products [redacted], defendants will be liable for inducing such direct infringement under 35 U.S.C. § 271(b).[3]

Dr. Hochberg also opines that because OA, RA, JRA and AS are all forms of arthritis, defendants will likewise induce direct infringement of claim 19 ("a method of treating arthritis") of the '048 patent, by selling their generic celecoxib products [redacted] for administration to patients to relieve the signs and symptoms of OA, RA, JRA and AS. In addition, Drs. Hochberg and Simon explain that because treating OA, RA, JRA, AS and PD with celecoxib relieves pain, which is a characteristic symptom of those conditions, defendants will also induce infringement of claim 20 ("a method of treating pain") on the part of patients who administer defendants' generic celecoxib products [redacted] to relieve the signs and symptoms of OA, RA, JRA and AS and to treat PD.

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[3] 35 U.S.C. § 271(b) states: "Whoever actively induces infringement of a patent shall be liable as an infringer."

As shown below, Pfizer is entitled to summary judgment on the issue of infringement. Pfizer's infringement contentions are fully supported by (1) the undisputed fact that defendants seek approval to market celecoxib for uses covered by the claims of the '048 patent; (2) the undisputed fact that, upon approval, defendants' generic celecoxib products will be marketed [redacted]; and (3) the testimony of eminent experts. Defendants have submitted no expert reports to the contrary and have raised no substantive defenses to infringement in their written discovery responses.[4] This Court should, therefore, grant summary judgment in Pfizer's favor, ruling that in marketing their generic celecoxib products [redacted], defendants will induce direct infringement of the '048 patent by patients as follows:

Indication Treated	**Inducing Defendants**	**Claims Infringed**
OA	[redacted]	19, 20, 21
RA	[redacted]	19, 20, 22
JRA	[redacted]	19, 20, 23
AS	[redacted]	19, 20, 24
AP	[redacted]	20
PD	[redacted]	20, 25

4 Nor may defendants raise such arguments at this point per Fed. R. Civ. P. 37(c) and the provisions of the Scheduling Order.

5 [redacted]

STATEMENT OF UNDISPUTED FACTS

The '048 Patent Claims

1. Defendants have submitted Abbreviated New Drug Applications ("ANDAs") to the U.S. Food and Drug Administration ("FDA") seeking approval to market generic versions of Pfizer's Celebrex® product. (Doc. 33, ¶ 77; Doc. 24, ¶ 67; Doc. 40, ¶ 63; Doc. 54, ¶ 82; Doc. 130, ¶ 72).

2. Defendants' proposed generic products contain celecoxib, the active ingredient in Celebrex®. (Doc. 33, ¶¶ 54, 77; Doc. 24, ¶¶ 54, 67; Doc. 40, ¶¶ 54, 63; Doc. 54, ¶¶ 54, 82; Doc. 130, ¶¶ 54, 72).

3. The '048 patent contains seven claims, all of which follow the same format. Claim 19 reads as follows:

> A method of treating arthritis in a subject, said method comprising administering to the subject having or susceptible to arthritis, a therapeutically-effective amount of 4-[5-(4-methylphenyl)-3-(trifluoromethyl)-1H-pyrazol-1-yl] benzenesulfonamide, or a pharmaceutically-acceptable salt thereof.

(Col. 110, lines 17-22).

4. Claims 20-25 are identical to claim 19 except that in those claims the term "arthritis" is replaced with "pain" in claim 20, "OA" in claim 21, "RA" in claim 22, "JA" in claim 23, "SpA" in claim 24, and "menstrual cramps" in claim 25. (Col. 110, lines 23-57).

5. The term "4-[5-(4-methylphenyl)-3-(trifluoromethyl)-1H-pyrazol-1-yl] benzenesulfonamide" is the chemical name for celecoxib. (Hochberg Rep. ¶ 47 n.76; Hamill-Ruth Rep. ¶ 25 n.17; Simon Rep. ¶ 36 n.10).[6]

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[6] Pfizer is submitting herewith declarations of Drs. Hochberg, Hamill-Ruth and Simon which adopt and incorporate by reference their expert reports on infringement. Citations are to the paragraphs in the expert reports which accompany the declarations.

6. The word "arthritis" -- which appears in claim 19 -- is used by physicians as an umbrella term that refers to joint diseases including OA, RA, JA and SpA. (Hochberg Rep. ¶ 16).

7. OA -- which appears in claim 21 -- is a form of chronic arthritis characterized by the breakdown of joint cartilage with related changes in the underlying bone, resulting in pain, stiffness and loss of function in the joint. (Hochberg Rep. at ¶ 19).

8. Pain, more than any other symptom, is what drives patients to seek assistance of a physician in treating their OA. (*Id.* at ¶ 24).

9. Celebrex® relieves the signs and symptoms of OA, including pain, inflammation and stiffness.

10. RA -- which appears in claim 22 -- is a chronic form of inflammatory arthritis. (Hochberg Rep. ¶ 25).

11. RA causes joint pain, stiffness, swelling and tenderness. (*Id.*)

12. Celebrex® provides relief of the signs and symptoms of the disease, including pain and swelling. (*Id.* at ¶ 29).

13. JA -- which appears in claim 23 -- is an umbrella term that refers to all rheumatic diseases in children associated with the development of arthritis. (Hochberg Rep. ¶ 31).

14. The most common form of JA is JRA. (*Id.*)

15. Drugs such as Celebrex® relieve the signs and symptoms of JRA including pain, stiffness and swelling. (*Id.* at ¶ 34).

16. SpA -- which appears in claim 24 -- refers to a group of related forms of inflammatory arthritis that typically affect the joints of the spine. (Hochberg Rep. ¶ 35).

17. AS is the most common SpA and primarily affects the sacroiliac joints (where the spine attaches to the pelvis), spine and hip joints. (*Id.* at ¶ 36).

18. Drugs such as Celebrex® are administered to SpA patients to relieve pain and stiffness and maintain the patient's range of motion. (*Id.* at ¶ 39).

19. Joint pain is a cardinal symptom of arthritis, including OA, RA, JRA and AS. (*Id.* at ¶ 112).

20. Celecoxib acts as an analgesic to relieve pain. ('048 patent, col. 4, line 56).

21. "Treating" the arthritis conditions of claims 19 and 21-24 involves relieving signs and symptoms of the conditions. (*Id.* at ¶ 89).

Defendants' Package Inserts

- **Indications**

[redacted]

[redacted]

- **Dosing**

[redacted]

- **Use of Defendants' Package Inserts/Labels**

28. Defendants have stipulated as follows with respect to the planned uses of their package inserts:

i. "When Apotex markets its celecoxib drug product, which is the subject of ANDA No. 204197, Apotex expects to make publicly available its FDA-approved package insert together with its celecoxib drug product." (Ex. 6).

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ii. "When Lupin markets its celecoxib drug product, which is the subject of ANDA No. 202240, Lupin expects to make publicly available its FDA-approved package insert together with its celecoxib drug product." (Ex. 7).

iii. "When Mylan markets its celecoxib drug product, which is the subject of ANDA No. 78-857, Mylan expects to make publicly available its FDA-approved package insert together with its celecoxib drug product." (Ex. 8).

iv. "In selling generic medications, Teva provides copies of the FDA-approved package insert together with the drug product and makes the package insert available through Teva's website." (Ex. 9).

v. [redacted]

POINT I

THE GOVERNING LAW

A. Patent Infringement

Pursuant to 35 U.S.C. § 271(e)(2): "It shall be an act of infringement to submit [an ANDA] for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval . . . to engage in the commercial manufacture, use or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent." According to the Federal Circuit, "infringement of method claims under § 271(e)(2) requires filing an ANDA wherein at least one 'use' listed in the ANDA is claimed in a patent." *AstraZeneca Pharm. LP v. Apotex Corp.*, 669 F.3d 1370, 1378 (Fed. Cir. 2012).

"Determining literal infringement is a two step process: the 'proper construction of the asserted claim and a determination whether the claim as properly construed reads on the accused product or method.'" *ActiveVideo Networks, Inc. v. Verizon Communications, Inc.*, 694 F.3d 1312, 1319 (Fed. Cir. 2012). *See also Hamilton Beach Brands, Inc. v. Sunbeam Prods., Inc.*, 2012 U.S. Dist. LEXIS 97923, at *7 (E.D. Va. 2012) ("To prove infringement, a patent holder must demonstrate that 'each and every limitation set forth in a claim appear[s] in an accused product.'").

"When a single actor commits all the elements of infringement, that actor is liable for direct infringement under 35 U.S.C. § 271(a). When a single actor induces another actor to commit all the elements of infringement, the first actor is liable for induced infringement under 35 U.S.C. § 271(b)." *Akamai Tech., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301, 1305 (Fed. Cir. 2012) (*per curiam*).

"[I]nducement requires that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement." *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1056 (Fed. Cir. 2010). In assessing the specific intent of an ANDA applicant, "[t]he pertinent question is whether the proposed label instructs users to perform the patented method. If so, the proposed label may provide evidence of . . . affirmative intent to induce infringement." *Id.* at 1060; *accord Eli Lilly & Co. v. Actavis Elizabeth LLC*, 435 F. App'x. 917, 926 (Fed. Cir. 2011) ("We have long held that the sale of a product specifically labeled for use in a patented method constitutes inducement to infringe that patent.").

B. The Summary Judgment Standard

"'The district court should only grant a motion for summary judgment where there is no genuine dispute as to an issue of material fact, and the moving party is entitled to summary judgment as a matter of law.'" *Hamilton Beach Brands, Inc. v. Sunbeam Prods., Inc.*, 726 F.3d 1370, 1374 (Fed. Cir. 2013). "It is the moving party's burden to show it is entitled to judgment as a matter of law, and the non-moving party's burden to 'demonstrate that a triable issue of fact exists; he may not rest upon mere allegations or denials. A mere scintilla of evidence supporting the case is insufficient.' In evaluating a motion for summary judgment, we view all evidence and draw all reasonable inferences from the evidence in a light most favorable to the non-moving party. 'Where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no "genuine issue for trial."'" *Fox Group, Inc. v. Cree, Inc.*, 700 F.3d 1300, 1303 (Fed. Cir. 2012) (citations omitted).

"Summary judgment on the issue of infringement is proper 'when no reasonable jury could find that every limitation recited in a properly construed claim either is or is not found in the accused device.'" *Hamilton Beach*, 2012 U.S. Dist. LEXIS 97923 at *7 (quoting

Fellowes, Inc. v. Michilin Prosperity Co., 491 F. Supp. 2d 571, 585 (E.D. Va. 2007), quoting *PC Connector Solutions LLC v. SmartDisk Corp.*, 406 F.3d 1359, 1364 (Fed. Cir. 2005)).

POINT II

CONSTRUCTION OF THE CLAIMS

Although this Court has, to date, not construed the claims of the '048 patent, Pfizer's experts make clear that by marketing their generic celecoxib products [redacted], defendants will, under any of the constructions proposed by the parties, induce direct infringement of the '048 patent by patients.

The preambles of claims 19-25 of the '048 patent recite "[a] method of treating [arthritis/pain/OA/RA/JA/SpA/menstrual cramps]." The parties have proposed that the preambles be construed as follows:

Claims 19, 21-24	**Claims 20, 25**
"A method of relieving the signs and symptoms of [arthritis/OA/RA/JA/SpA]"	"A method of relieving [pain/menstrual cramps]"
"A method of relieving the signs or symptoms of [arthritis/OA/RA/JA/SpA]"	
"A method of medically caring for or dealing with [arthritis/OA/RA/JA/SpA]"	"A method of medically caring for or dealing with [pain/menstrual cramps"[8]

[8] Defendants Lupin and Apotex have taken the position that in the context of the claims of the '048 patent the preamble cannot be construed. Mylan and Watson maintain that no construction of the preamble language is required.

The bodies of the claims of the '048 patent recite "administering to the subject having or susceptible to [arthritis/pain/OA/RA/JA/SpA/menstrual cramps], a therapeutically effective amount of [celecoxib]." The parties have proposed the following constructions:

Claims 19, 21-24	**Claims 20, 25**
"administering to the subject having or susceptible to the signs and symptoms of [arthritis/OA/RA/JA/SpA], a therapeutically-effective amount of [celecoxib]"	"administering to the subject having or susceptible to [pain/menstrual cramps], a therapeutically-effective amount of [celecoxib]"
"administering to the subject who has developed or is at risk of developing [arthritis/OA/RA/JA/SpA], a therapeutically-effective amount of [celecoxib]"	"administering to the subject who has developed or is at risk of developing [pain/menstrual cramps], a therapeutically-effective amount of [celecoxib]"
"administering to the subject currently experiencing or predisposed, liable or sensitive to the effects of [arthritis/OA/RA/JA/SpA], a therapeutically-effective amount of [celecoxib]"	

POINT III

ADMINISTRATION OF DEFENDANTS' GENERIC CELECOXIB PRODUCTS [redacted] WILL DIRECTLY INFRINGE THE CLAIMS OF THE '048 PATENT

A. The Arthritis Indications Infringe Claims 19, 21-24 (Arthritis, OA, RA, JA and SpA) and 20 (Pain)

A patient using each defendant's generic celecoxib product, [redacted] for relief of the signs and symptoms of OA, RA, JRA and AS will, *under any of the constructions proposed by the parties*, perform each step

of the claimed methods and thus directly infringe claims 19-24 of the '048 patent. (Hochberg Rep. ¶ 83).[9]

1. Administration of defendants' products to treat OA, RA, JRA and AS will directly infringe claims 19 and 21-24.

As Dr. Hochberg explains, "treating" the arthritis conditions of claims 19 and 21-24 involves relieving signs and symptoms of the conditions. (*Id.* at ¶ 89). In the context of treating the arthritis conditions specified in those claims, per the preambles of those claims, "relieving the signs and/or symptoms" of the condition and "medically caring for or dealing with" the condition -- the parties' proposed constructions -- are synonymous. (*Id.*) Because OA, RA, JRA and AS are all forms of arthritis, a patient administering each defendant's generic celecoxib product [redacted] to relieve the signs and symptoms of OA, RA, JRA and AS will directly perform "a method of treating arthritis" as set forth in the preamble of claim 19. In addition, patients administering defendants' generic products [redacted] for relief of the signs and symptoms of OA, RA, JA, and SpA, will perform the "method[s] of treatment" recited in the preambles of claims 21, 22, 23 and 24 respectively.

Under any of the parties' proposed constructions of the phrase "administering to the subject having or susceptible to [arthritis/OA/RA/JA/SpA]" in claims 19 and 21-24, the subjects to whom physicians will prescribe defendants' celecoxib products [redacted], to relieve the signs and symptoms of OA, RA, JRA and

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[9] Dr. Marc C. Hochberg heads the Division of Rheumatology & Clinical Immunology and a Professor of Medicine and Epidemiology & Public Health at the University of Maryland School of Medicine. Dr. Hochberg is a board certified rheumatologist and has been practicing for 36 years. More biographical information about Dr. Hochberg is included in paragraphs 1-9 of his report and in Ex. 1 thereto.

AS, will be persons "having or susceptible to" arthritis, OA, RA, JA and SpA per the claims. (Hochberg Rep. ¶ 103). Those subjects will be persons "having," "susceptible to," "currently experiencing," "currently experiencing the signs and symptoms of," "susceptible to the signs and symptoms of," "predisposed, liable or sensitive to the effects of," or "who have developed or are at risk of developing" arthritis, OA, RA, JA or SpA. (*Id.*) Furthermore, administration of defendants' generic celecoxib products for relief of the signs and symptoms of OA, RA, JRA and/or AS, [redacted] constitutes administration of a therapeutically-effective amount of celecoxib for relief of the signs and symptoms of OA, RA, JRA or AS. (*Id.* at ¶¶ 105-06). Consequently, under any of the parties' proposed constructions of claims 19 and 21-24, a patient's use of defendants' generic products to relieve the signs and symptoms of OA, RA, JRA and/or AS [redacted] will directly perform the step of "administering to the subject having or susceptible to [arthritis/OA/RA/JA/SpA] a therapeutically-effective amount of [celecoxib]." (*Id.* at ¶ 108).

2. Administration of defendants' products to treat OA, RA, JRA and AS will directly infringe claim 20.

Dr. Hochberg further states that a patient's use of each defendant's generic celecoxib products [redacted] for relief of the signs and symptoms of OA, RA, JRA or AS, will practice the steps of claim 20 of the '048 patent and thus directly infringe claim 20. (Hochberg Rep. ¶ 109). According to Dr. Hochberg, joint pain is a cardinal symptom of arthritis, including OA, RA, JRA and AS. (*Id.* at ¶ 112). The vast majority of arthritis patients see their rheumatologist specifically seeking help for arthritis-related pain. (*Id.*) Even those arthritis patients with a different primary complaint tend to suffer at least intermittently from pain. (*Id.*) As set forth in the '048 patent, celecoxib acts as an

analgesic to relieve pain. (Col. 4, line 56). Hence, when prescribed by a physician and self-administered by a patient for relief of the signs and symptoms of OA, RA, JRA and AS, [redacted] defendants' generic celecoxib products will relieve the pain of those arthritis conditions. (Hochberg Rep. ¶ 115). Dr. Hochberg opines that under any of the proposed constructions of the claims, a patient using each defendant's generic product [redacted] for relief of the signs and symptoms of OA, RA, JRA or AS, will perform the "method of treating pain" recited in the preamble of claim 20 of the '048 patent as well as the step of "administering to the subject having or susceptible to pain a therapeutically-effective amount of [celecoxib]" recited in the body of claim 20. (*Id.* at ¶¶ 117, 124, 128).

B. <u>The Acute Pain Indication Infringes Claim 20 (Pain)</u>

A patient using any of defendants' generic products for management of acute pain (AP) [redacted] will perform each step of the method of claim 20 of the '048 patent and thus directly infringe claim 20, *under any construction of claim 20 proposed by the parties*. (Hamill-Ruth Rep. ¶¶ 54, 63).[10] In particular, whether the preamble of claim 20 is construed to mean "a method of relieving pain" or "a method of medically caring for or dealing with pain," a patient using defendants' generic celecoxib products for the management of AP will directly perform "a method of treating pain," as recited in the preamble of claim 20. (*Id.* at ¶ 65).

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[10] Dr. Robin J. Hamill-Ruth is co-director of the Pain Management Center and an associate Professor of Anesthesiology and Critical Care at the University of Virginia Health Sciences Center ("UVA"). Dr. Hamill-Ruth is also Director of Clinical Pain Research at UVA. She has practiced in the field of pain medicine for more than 26 years. More biographical information about Dr. Hamill-Ruth is included in ¶¶ 1-5 of her report and in Exhibits 1A and 1B thereto.

Likewise, under any proposed construction of the body of claim 20, a patient prescribed and administering celecoxib for management of AP will be within the subjects "having or susceptible to pain" as identified in the claim. In other words, those subjects will be persons "having pain," "currently experiencing pain," "susceptible to pain," "predisposed, liable or sensitive to the effects of pain," "who have developed pain" or "at risk of developing pain." (*Id.* at ¶ 74). Furthermore, [redacted] physicians will prescribe defendants' products for the management of AP in therapeutically effective amounts based on the patient's needs. (*Id.* at ¶¶ 77-79). Therefore, under any of the parties' proposed constructions, administration of defendants' products [redacted] for the management of AP, will constitute "administering to the subject having or susceptible to pain, a therapeutically-effective amount of [celecoxib]," as recited in claim 20. (*Id.* at ¶ 80).

C. <u>The PD Indication Infringes Claim 20 (Pain) and Claim 25 (Menstrual Cramps)</u>

A patient using defendants' generic celecoxib products [redacted] to treat PD [redacted] will perform the methods of claims 20 ("method of treating pain") and claim 25 ("method of treating menstrual cramps") of the '048 patent and will thus directly infringe those claims, *under any of the claim constructions proposed by the parties*. (Simon Rep. ¶ 72).[11] Dr. Simon explains that a woman using defendants' generic celecoxib products to treat PD [redacted] will be treating menstrual cramps as recited in the preamble of claim 25, under any proposed

[11] Dr. James Simon is a clinical professor in the Department of Obstetrics and Gynecology at the George Washington University School of Medicine. He is board certified in obstetrics and gynecology and has practiced in the field for almost 30 years. More biographical information about Dr. Simon is included in ¶¶ 1-7 of his report and in Exs. 1A and 1B thereto.

construction of the preamble. (*Id.* at ¶ 74). In addition, a patient using defendants' generic celecoxib products to treat PD [redacted] will be, under any of the parties' proposed constructions, a subject "having or susceptible to" menstrual cramps as recited in claim 25. (*Id.* at ¶ 86). The patient will be a subject "having menstrual cramps," "susceptible to menstrual cramps," "predisposed, liable or sensitive to the effects of menstrual cramps," "currently experiencing menstrual cramps," "who has developed menstrual cramps" or "is at risk of developing menstrual cramps." (*Id.*) Moreover, administering defendants' generic celecoxib products to treat PD [redacted] will constitute administration of a therapeutically-effective amount of celecoxib. (*Id.* at ¶ 87). As a result, a patient administering defendants' generic celecoxib products for the treatment of PD will be "administering to the subject having or susceptible to menstrual cramps, a therapeutically-effective amount of [celecoxib]" as recited in claim 25.

Furthermore, according to Dr. Simon, a patient administering defendants' generic celecoxib products to treat PD [redacted] will perform the steps of claim 20 of the '048 patent and thus directly infringe claim 20. (Simon Rep. ¶ 72). Administering defendants' generic celecoxib products to treat PD will relieve the pain of PD. (*Id.* at ¶ 91). Relieving menstrual cramps constitutes treating pain, relieving pain, and medically caring for or dealing with pain. (*Id.* at ¶ 93). Thus, under any proposed construction of the preamble of claim 20, administering defendants' celecoxib products to treat PD [redacted] performs "a method of treating pain" as set forth in the preamble of claim 20.

Moreover, patients prescribed defendants' generic celecoxib products to treat PD [redacted] will be subjects "having or susceptible to pain" as set forth in claim 20. (Simon Rep. ¶ 96). The patient will be a subject

"having pain," "susceptible to pain," "predisposed, liable or sensitive to the effects of pain," "currently experiencing pain," "who has developed pain," or "is at risk of developing pain." (*Id.* at ¶ 105). Additionally, administering defendants' generic celecoxib products to treat PD [redacted] will constitute administering "a therapeutically-effective amount of celecoxib." (*Id.* at ¶ 106). Consequently, administering defendants' generic celecoxib products for the treatment of PD [redacted] will constitute "administering to the subject having or susceptible to pain, a therapeutically-effective amount of [celecoxib]." (*Id.* at ¶ 107).

POINT IV

IN SELLING THEIR GENERIC CELECOXIB PRODUCTS [redacted], DEFENDANTS WILL INDUCE DIRECT INFRINGEMENT OF CLAIMS 19-25 OF THE '048 PATENT

Administration of defendants' generic celecoxib products [redacted] constitutes direct infringement of claims 19-25 of the '048 patent. Therefore, when, upon approval, defendants sell their generic celecoxib products [redacted], defendants will induce that direct infringement by patients. *See AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1059-60 (Fed. Cir. 2010). As a result, defendants will be liable for infringement of the '048 patent under 35 U.S.C. § 271(b). The Court should grant summary judgment accordingly.

CONCLUSION

Based on the foregoing, this Court should grant summary judgment in favor of Pfizer, holding that by selling their generic celecoxib products [redacted], defendants will induce infringement of the '048 patent as follows:

Indication Treated	Inducing Defendants	Claims Infringed
OA	[redacted]	19, 20, 21
RA	[redacted]	19, 20, 22
JRA	[redacted]	19, 20, 23
AS	[redacted]	19, 20, 24
AP	[redacted]	20
PD	[redacted]	20, 25

Dated: November 22, 2013

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 22, 2013, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will automatically e-mail notification of such filing to:

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